Magnetic Anchoring and Guidance System Instrumentation for Laparo-endoscopic Single-site Surgery/Natural Orifice Transluminal Endoscopic Surgery: Lack of Histologic Damage After Prolonged Magnetic Coupling Across the Abdominal Wall

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OBJECTIVES To study the potential pathologic effect of prolonged compression of abdominal wall between the components. Magnetic Anchoring and Guidance System (MAGS) instruments ameliorate some of the challenges in triangulation created by laparo-endoscopic single-site and natural orifice translumenal endoscopic surgery. They consist of an intracorporeal magnetic device coupled to an external hand-held magnet used to anchor and "steer" it around the peritoneal cavity.

METHODS Three pigs (45.5-48.6 kg) underwent laparoscopic placement of magnetic devices in 4 quadrants, with the devices left in place for 2 or 4 hours. Full-thickness abdominal wall sections (mean 2.1 cm thick) where each MAGS platform was placed plus a control were harvested at 0, 2, or 14 days after surgery. Histologic assessment was then performed.

RESULTS Beyond mild blanching of the peritoneal surface with a few petechiae immediately after internal component removal, no gross tissue damage was seen. These changes were undetectable by 48 hours and no intra-abdominal adhesions were identified at necropsy. NADH stain for tissue viability in the 4 nonsurvival specimens showed no tissue damage. Hematoxylin and eosin stain showed no necrosis of either superficial or deep muscle, skin, or subcutaneous fat tissue in all 12 specimens when compared with the control.

CONCLUSIONS MAGS instruments do not appear to cause tissue damage or adverse clinical outcomes when coupled across thin porcine abdominal walls for up to 4 hours. Because the distance across the abdominal wall is generally greater in adult human beings, these findings support the further clinical development of magnetic instruments to be used in human patients. UROLOGY 77: 243–247, 2011. © 2011 Elsevier Inc.

In recent years, alternatives to conventional laparoscopic surgery have emerged, including natural orifice transluminal endoscopic surgery (NOTES) and laparo-endoscopic single-site surgery (LESS). These techniques attempt to minimize the invasiveness of surgery by reducing the number of transabdominal port sites. A number of series have reported the safety of these surgeries in urology,[1-8] but these techniques remain plagued by technical challenges that have kept them from "taking hold" in mainstream urology. The main difficulty stems from the fact that, in passing all of the instruments through a single access point, the instruments are prone to collisions and unfamiliar working angles.

To help address some of these challenges, we have developed a technology termed Magnetic Anchoring and Guidance System (MAGS), which consists of magnetic instruments that, once inserted through an access port, can be driven into position inside the peritoneal cavity through magnetic attraction to an external, hand-held magnet. This way, instruments, such as cameras, retractors, and cautery devices can be placed in ergonomically favorable locations without having to make a separate incision through the abdominal wall. The magnetic

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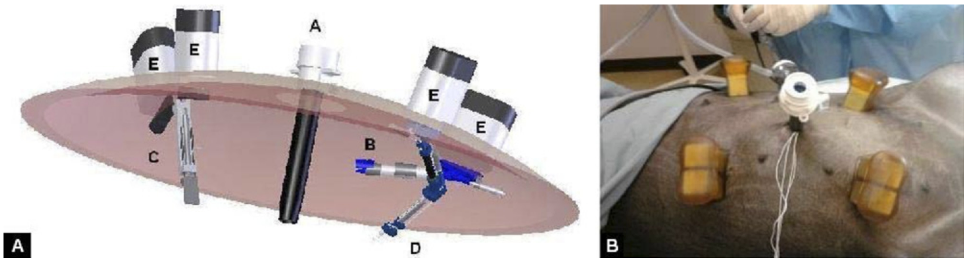

Figure 1. **(A)** Schematic representation of Magnetic Anchoring and Guidance System (MAGS) platform. One conventional trocar is depicted with 4 deployed MAGS instruments: (A) deployment trocar; (B) MAGS camera; (C) retractors; (D) robotic cauterizer; and (E) hand-held external magnets. **(B)** External view of pig with all 4 MAGS platforms in place, in each of the 4 abdominal quadrants. Orange devices are extracorporeal, hand-held magnets.

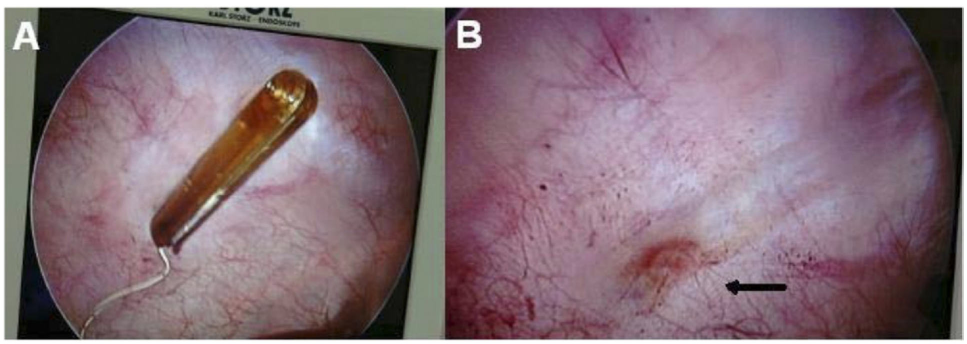

Figure 2. Laparoscopic view of the anterior abdominal wall/peritoneal surface before **(A)** and after **(B)** removal of the intracorporeal MAGS cautery device. Note mild blanching of peritoneal surface and the petechiae.

forces between the intra- and extracorporeal magnets keep the internal instrument suspended from the anterior abdominal wall (Fig. 1).

In keeping with the internal and external magnetic components of the device coupled together, however, the abdominal wall is essentially "pinched" between the 2 magnets. Previous studies using these instruments in both survival and nonsurvival animal models have not reported any gross evidence of tissue damage in the subjects[9-15]; however before pursuing development of these instruments for further use in human patients, it is important to evaluate the histologic effects of these instruments on the abdominal wall.

MATERIAL AND METHODS

After obtaining approval from the institutional animal care and use committee, 3 domestic pigs (45.5-48.6 kg) underwent general anesthesia and were placed in the supine position. A Veress needle was used to obtain a CO_2 pneumoperitoneum at the level of the umbilicus, and a 12-mm laparoscopic port was placed. A pneumoperitoneum pressure of 15 mm Hg was maintained and the internal components of 4 identical prototype MAGS cautery dissector devices (14 mm in diameter and 71 mm in length, 36.5 g), manufactured by Ethicon Endosurgery, Inc. (Cincinnati, OH), were inserted 1 at a time through the port and into the peritoneal cavity. Once the internal device was inside, a laparoscopic camera was inserted through the port and was used to visualize the coupling between the internal and external components. The hand-held extracorporeal magnet was held against the external abdominal wall, which "attracted" the internal element, fixing it to the anterior peritoneal surface. Once this had occurred, the hand-held magnet was used to steer the internal device into position within the peritoneal cavity. This was performed for each of the 4 devices, positioning 1 pair into each of the 4 quadrants of the abdomen (Figs. 1 and 2). After positioning, the devices were left in place for either 2 or 4 hours. When it was time to remove them, the internal magnetic cautery device was steered back into the transabdominal port and removed, again using the external magnet for manipulation.

Before removal, the location of the magnets was marked out on the external abdominal wall for future reference. The animals were euthanized at 3 different time points, 1 animal immediately after surgery and 1 each at 2 and 14 days after surgery. The abdomen was opened and any gross tissue damage was noted, as was the presence or absence of intra-abdominal adhesions. The 12 full-thickness abdominal wall segments were then harvested, corresponding to the 12 premarked magnet positions. An additional abdominal wall segment was harvested from an area where MAGS devices were not placed, and this served as a control. After measuring the abdominal wall thickness of each specimen, the specimens were sent for histologic analysis by a board-certified pathologist who was blinded to the duration of magnetic coupling.

Specimens were serially sectioned, perpendicular to the skin surface to reveal the underlying subcutaneous and skeletal muscle. A thorough examination for areas of necrosis or discoloration was performed. If no abnormality was noted, multiple random sections of skin, subcutaneous tissue and muscle were submitted. Paraffin-embedded, hematoxylin and eosin (H&E)

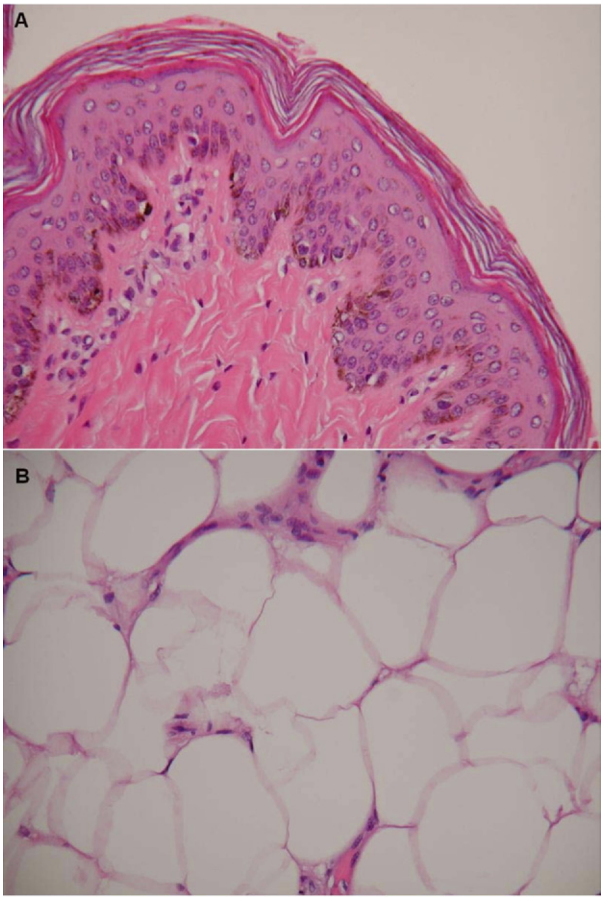

Figure 3. Histopathology of skin **(A)** and subcutaneous tissues **(B)** showing no ulceration, fat necrosis or inflammation. H&E, ×200.

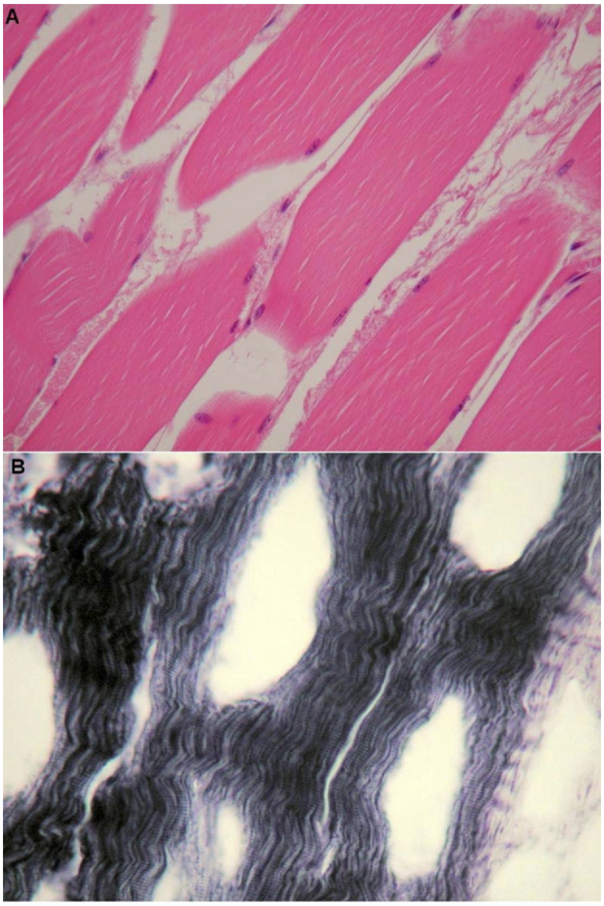

Figure 4. Skeletal muscle, ×200. **(A)** H&E stain, no necrosis, inflammation, or atrophy is noted. **(B)** NADH staining (for tissue viability, nonsurvival subject only). Normal staining pattern demonstrates that tissue remains viable.

–stained sections were examined for all specimens. In the nonsurvival animal, where cellular viability may not have been accurately evaluated with H&E sections alone, the analysis included NADH staining. Multiple samples were submitted for cryo sectioning (−20 C) and immediately transferred to pathology to perform NADH staining.

The following histologic parameters were used to assess muscle necrosis: sarcolemmal nuclear displacement or loss, mononuclear infiltration, muscle fiber splitting, variation in muscle size (ischemic atrophy), hyaline degeneration, and cytoplasmic vacuolization. In addition, the presence of acute inflammation, fat necrosis, skin ulceration and vascular congestion was noted.

RESULTS

Laparoscopic placement, coupling, and removal of MAGS instruments occurred without complication in all 3 pigs. Upon removal of the internal MAGS components, laparoscopic examination of the peritoneal surface where the instrument had been positioned revealed mild blanching of the tissue, as well as a few small petechiae (Fig. 2). There was no bruising of the skin seen externally either immediately or in the subsequent days during recovery. The 2 survival animals recovered without incident. Necropsy showed no intra-abdominal adhesions in any of the pigs. By the time of the necropsy of the 2- and 14-day survival animals, the peritoneal changes seen immediately after magnet removal (mild blanching/petechiae) had completely resolved and the tissues appeared normal.

The abdominal wall segments were measured for thickness at the time of harvest. The abdominal wall thickness for all 12 specimens ranged from 1.3 to 2.9 (mean 2.1 cm). The porcine abdominal wall has been found to compress 20%-40% when pinched between the magnets (nonpublished data), so the actual estimated mean distance between the external and internal components in situ on the abdominal wall was approximately 1.5 cm (range 0.9-2.1 cm). Ex vivo testing demonstrated that the pressures generated by these magnets (range 0.88-6.78 psi across the stated distances) at 1.5 and 2.1 cm distance are 3.45 and 1.87 psi, respectively.

Pathologic assessment confirmed that all tissues appeared grossly normal. On microscopic examination (compared with control), all tissue sections demonstrated no evidence of skeletal muscle or skin necrosis or atrophy (Figs. 3 and 4). No ulceration, acute inflammation, or granulation tissue formation, fat necrosis, or vascular congestion was noted. NADH staining of the 4 specimens from the nonsurvival animal was normal, demonstrating viability of the tissues (Fig. 4B).

COMMENT

Traditional laparoscopy is usually performed through 3 or more transabdominal port sites, each of which carries the risk of port site bleeding, hernia, or internal organ injury as well as increased number of scars.[16-19] Because of these risks, some surgeons have been pursuing even less invasive forms of laparoscopic surgery that use only 1 transabdominal port site (i.e., LESS) or altogether move access to a natural orifice (i.e., NOTES). Thus, NOTES and LESS attempt to minimize abdominal wall incisions, which may help to mitigate some of these risks. In NOTES, operative instruments are passed through an opening created in a natural orifice, such as the stomach, colon, or vagina, leaving the patient with no visible scars. Similarly, LESS surgery involves passing all of the surgical instruments through a single transabdominal incision, often at the umbilicus, where the scar can be hidden.

However, these techniques are not without challenges of their own. The primary reason for the use of multiple ports spaced out across the abdominal wall in traditional laparoscopy is that this spacing preserves one of the main tenets of laparoscopic surgery: triangulation. In NOTES and LESS surgery, however, all instruments are passed into the abdomen through a single entry point. Not only does this substantially decrease triangulation, but the instruments compete for the same working space and can collide with each other. These differences can make these procedures very challenging even to experienced laparoscopic surgeons.

To address these issues, some researchers are developing technologies to deploy instruments inside the body without having them occupy port site space. One method being explored harnesses magnetic forces to steer and operate completely insertable intracorporeal instruments via externally-controlled magnets. This technology (i.e., MAGS) includes cameras, retractors, dissectors, cautery devices, and even combinations thereof (Fig. 1). These instruments are inserted into the abdomen through the access site (be it NOTES or LESS) and then are suspended from the anterior abdominal wall through magnetic attraction to an external hand-held magnet. By moving the hand-held magnet over the skin to a different position on the abdomen, the intracorporeal instrument is also moved to a different location within the peritoneal cavity.[9-15,20,21]

There have been several reports of MAGS technology,[9-15,20,21] culminating in use in human cases. The largest series of human cases, by Dominguez et al,[22] describes using "neodymium magnetic forceps" to perform 40 human LESS cholecystectomies. These instruments consist of an internal magnet attached to a flexible alligator grasper head. The grasper is passed intracorporeally and used to elevate the gallbladder via coupling with a large external magnet. They report no magnet-related complications or conversions in these 40 patients. Our multidepartmental consortium has reported LESS nephrectomy and appendectomy, each once in human patients.[10] Despite these encouraging results with no report of magnet-related abdominal wall complications, to date no study has been done of the actual tissue effects.

Because this technology works through the maintenance of attraction between 2 magnets separated by the abdominal wall, we were concerned that the resulting compression of the tissue might cause damage, and therefore sought to determine the effect of this compression over time. In this study, we used a MAGS cautery dissector prototype that is being developed for commercial release; thus a representative instrument was used, incorporating realistic elements of attraction force and surface area. Although the MAGS instruments used in our study did cause mild blanching and petechiae of the porcine peritoneum, it is reassuring that, even with 4 hours of constant compression at an estimated mean 3.45 psi, there was no immediate or long-term tissue damage seen on histologic analysis. In addition, because porcine abdominal walls are thinner (mean uncompressed thickness, 2.1 cm) than those of many adult human patients, and because magnetic attraction decreases exponentially with increasing distance, the compressive force experienced by human patients with the current tool embodiments would be less than that generated in this experiment. Thus this study demonstrated no pathologic damage under more severe compressive conditions than would be expected during surgery in a human patient, including a greater force applied to a constant area, across a shorter-distance, and over a long period. Importantly, there were no adverse clinical outcomes as well; specifically, we did not detect any intra-abdominal adhesions in the survival animals. Future instrument development may aim to design magnets with an adjustable attraction force such that the force between components remains constant during use. Such magnets could decrease their attraction when the instruments are separated by a short distance (i.e., a thin abdominal wall) or increase it when encountering a wider distance or when other forces, such as friction, are threatening to separate the components.

It is important to note that, beyond the initial placement into position, the MAGS instruments in this study were not manipulated in a way that was designed to mimic their surgical use. Although the forces between the 2 magnets are strongest when they are at rest, such as in our study design, it is possible that repetitive movement of the paired magnets might cause different tissue effects. For example, using a cautery dissector device could conceivably cause local tissue trauma through mechanical and abrasive forces; we plan to evaluate the MAGS instruments under these conditions. Finally, our study endpoint was limited to a compression time of 4 hours and longer periods were not studied; however 4 hours is certainly a clinically relevant duration for many operations.

CONCLUSIONS

MAGS instruments do not appear to cause tissue damage or adverse clinical outcomes when coupled across thin porcine abdominal walls for up to 4 hours. The porcine

abdominal wall tolerated a maximum pressure of 6.78 psi even when compressed across the shortest distance of 0.9 cm. Because the distance across the abdominal wall is generally greater in adult human beings, these findings support the further clinical development of magnetic instruments to be used in human patients.

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